Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (Text with EEA relevance)

Article 8

Operating of designating authorities

1 Designating authorities shall have a sufficient number of competent personnel at their disposal for the proper performance of their tasks. Those authorities shall be established, organised and operated so as to safeguard the objectivity and impartiality of their activities and to avoid any conflicts of interests with conformity assessment bodies. The designating authorities shall be organised so that each decision relating to a notification of a conformity assessment body is not taken by the same member of personnel who carried out the assessment of that body.

2 Where designating authorities are not in charge of market surveillance and vigilance for medical devices, they shall involve the competent authorities of that Member State for all tasks incumbent to them in accordance with this Regulation. They shall in particular consult the competent authorities of that Member State prior to taking decisions and invite them to attend all types of assessments.